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LB

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 02202004

Application Number: 10/007,272
Filing Date: October 29, 2001
Appellant(s): GLOVER ET AL.

Lorie Ann Morgan
For Appellant

## EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed October 1, 2003.

***(1) Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

***(2) Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

***(3) Status of Claims.***

The statement of the status of claims contained in the brief is correct.

***(4) Status of Amendments After Final.***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

***(5) Summary of Invention.***

The summary of invention contained in the brief is correct.

***(6) Issues.***

The appellant's statement of the issues in the brief is correct.

***(7) Grouping of Claims.***

The brief includes a statement that claims **11, 14 and 16-21** do not stand or fall together but fails to present reasons in support thereof. Therefore, these claims are presumed to stand or fall together.

***(8) Claims Appealed.***

The copy of the appealed claims contained in the Appendix to the brief is correct.

*(9) Prior Art of Record.*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

| Number | Name | Date |
|---|---|---|
| **6,077,832 A** | Chamberlain et al. | June 20; 2000 |

*(10) Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims. Alternatively, claims **11, 14 and 16-21** are rejected under 35 U.S.C. §102(e) as fully set forth in the prior Office action, Paper No. **09**.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

Claims **11, 14 and 16-21** are rejected under 35 U.S.C. §102(e) as being anticipated by **Chamberlain et al. '832** (PTO-1449 ref. **AK**).

Applicant is referred to claims ***20-23*** (pharmaceutical compositions) and claims ***26-28*** (methods of treating herpes viral infections) of the **'832** reference wherein the instant claimed subject matter has been anticipated. The particular crystal structure, mixture of crystal structures, or absence of crystal structure of the active ingredient is deemed to be irrelevant to the pharmaceutical efficacy thereof because

i) the pharmaceutical activity of the active ingredient is a function of the molecular structure(s) adsorbed by the cells contacted by the composition and/or
ii) the crystal structure is destroyed by dissolution of the crystalline solid by the pharmaceutically acceptable carrier.

***(11) Response to Argument.***

Applicant admits that the '832 patent qualifies as prior art under 35 U.S.C. §102(**e**). However, applicant asserts lack of anticipation and has argued in support of this view on the basis that the instant claims include limitations not found in the cited reference. Examiner respectfully disagrees.

The treatment of any herpes simplex viral disease condition does not occur via contact of any one crystalline form of the solid compound specified herein, but does occur at the molecular level following complete dissolution of the active ingredient either by the pharmaceutical carrier or by one of the human circulatory fluids, or a combination thereof. Therefore, the biological activity of the active ingredient cannot be a function of the particular orientation of molecules in a particular crystalline form. For this reason examiner concludes that the crystallographic limitations applicant alleges are critical to the patentability of the instant claims over the cited prior art are in fact not critical.

As to the technical issue of whether the instant claims are anticipated, examiner argues that said claims are anticipated because the biological activity of the pharmaceutical compositions being claimed, and the biological activity relied upon by the methods of treatment of herpes virus infections being claimed, are both identical with the activity relied upon by the prior art disclosure. Therefore, while the instant claims are not identical with the prior art disclosure, they are effectively anticipated because the alleged basis for distinction over the prior art, the specific crystalline form of the active ingredient, has no effect whatsoever on the inherent biological activity (anti-herpes virus activity) of the molecules of the active ingredient. Examiner also notes that applicant has admitted that this is true: see applicant's response of March 6, 2003 at page 4, paragraph 2, first sentence.

And lastly, examiner notes that applicant has not alleged, or provided any factual disclosure supporting any unexpected technical or other advantage associated with one or more of the crystalline forms or any mixture including same specified in any single pharmaceutical

composition or method of treatment claim.

Therefore, Examiner concludes that grant of a patent would unfairly extend the coverage already provided to the common assignee by the '832 patent because the differences found in the instant claims when compared with the claims of the '832 patent vanish when the effective ingredient is called upon to carry out its pharmaceutical role in either the formation of a pharmaceutical composition wherein the carrier dissolves the active ingredient and thereby destroys all crystal structures, or in the treatment of herpes virus infections with said composition.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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